1615

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	09/778,154
Filing Date	February 5, 2001
First Named Inventor	Seo Hong Yoo
Group Art Unit	1615
Examiner Name	Vickie Kim
Total Number of Pages in This Submission: 15	Attorney Docket Number: APAP31191-A 072852.0117

ENCLOSURES *(check all that apply)*

- [x] Fee Transmittal Form
  - [ ] Fee Attached
- [ ] Amendment / Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Response to Missing Parts/ Incomplete Application
  - [ ] Response to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Assignment Papers *(for an Application)*
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
- [ ] After Allowance Communication to Group
- [ ] Appeal Communication to Board of Appeals and Interferences
- [ ] Appeal Communication to Group *(Appeal Notice, Brief, Reply Brief)*
- [ ] Proprietary Information
- [ ] Status Letter
- [x] Other Enclosure(s) *(please identify below)*:

Election letter (5 sheets);
Copy of Informal Office Communication faxed to Applicant's Attorney on May 29, 2002; and
Return postcard

Remarks [ ]

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	BakerBotts LLP 30 Rockefeller Plaza New York, NY 10112
Signature	Att Name: Neil P. Sirota PTO Reg: 38,306
Date	September 19, 2002

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on this date: September 19, 2002

Typed or printed name	Neil P. Sirota		
Signature		Date	September 19, 2002

BAKER BOTTS LLP

FEE TRANSMITTAL for FY 2002

Patent fees are subject to annual revision.

TOTAL AMOUNT OF PAYMENT ($) 0

Complet if Known	
Application Number	09/778,154
Filing Date	February 5, 2001
First Named Inventor	Seo Hong Yoo
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Group Art Unit	1615
Attorney Docket No.	APAP31191-A 072852.0117

METHOD OF PAYMENT

1. ☐ The Commissioner is hereby authorized to charge indicated fees and credit any overpayments to:

Deposit Account Number: 02-4377

Deposit Account Name: Baker Botts LLP

☑ Charge Any Additional Fee Required Under 37 CFR 1.16 and 1.17

☐ Applicant claims small entity status. See 37 CFR 1.27

2. ☐ **Payment Enclosed:**

☐ Check ☐ Credit card ☐ Money Order ☐ Other

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee ($)	Small Entity Fee ($)	Fee Description	Fee Paid
740	370	Utility filing fee	
330	165	Design filing fee	
510	255	Plant filing fee	
740	370	Reissue filing fee	
160	80	Provisional filing fee	

SUBTOTAL (1) ($) 0

2. EXTRA CLAIM FEES

		Extra Claims		Fee from below	Fee Paid
Total Claims	- 20** =	0	X		0
Independent Claims	- 3** =	0	X		0
Multiple Dependent					

Large Entity Fee ($)	Small Entity Fee ($)	Fee Description
18	9	Claims in excess of 20
84	42	Independent claims in excess of 3
280	140	Multiple dependent claim, if not paid
84	42	** Reissue independent claims over original patent
18	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) 0

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee ($)	Small Entity Fee ($)	Fee Description	Fee Paid
130	65	Surcharge - late filing fee or oath	
50	25	Surcharge - late provisional filing fee or cover sheet	
130	130	Non-English specification	
2,520	2,520	For filing a request for *ex parte* reexamination	
920*	920*	Requesting publication of SIR prior to Examiner action	
1,840*	1,840*	Requesting publication of SIR after Examiner action	
110	55	Extension for reply within first month	
400	200	Extension for reply within second month	
920	460	Extension for reply within third month	
1,440	720	Extension for reply within fourth month	
1,960	980	Extension for reply within fifth month	
320	160	Notice of Appeal	
320	160	Filing a brief in support of an appeal	
280	140	Request for oral hearing	
1,510	1,510	Petition to institute a public use proceeding	
110	55	Petition to revive - unavoidable	
1,280	640	Petition to revive - unintentional	
1,280	640	Utility issue fee (or reissue)	
460	230	Design issue fee	
620	310	Plant issue fee	
130	130	Petitions to the Commissioner	
50	50	Processing fee under 37 CFR 1.17(q)	
180	180	Submission of Information Disclosure Stmt	
40	40	Recording each patent assignment per property (times number of properties)	
740	370	Filing a submission after final rejection (37 CFR § 1.129(a))	
740	370	For each additional invention to be examined (37 CFR § 1.129(b))	
740	370	Request for Continued Examination (RCE)	
900	900	Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($) 0

SUBMITTED BY				Complete *(if applicable)*	
Name (Print/Type)	Neil P. Sirota	Registration No. (Attorney/Agent)	38,306	Telephone	(212) 408-2548
Signature				Date	September 19, 2002

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

BAKER BOTTS LLP

Attorney Docket Number: APAP31191-A 072852.0117

Title: PREPARATION OF AQUEOUS CLEAR SOLUTION DOSAGE FORMULATIONS WITH BILE ACIDS

Use Space Below for Additional Information:

Application No.	Applicant(s)	
09/778,154	YOO, SEO HONG	
Examiner	Art Unit	
Vickie Kim	1614	

Office Action Summary

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on ____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-147* is/are pending in the application.

4a) Of the above claim(s) ____ is/are withdrawn from consideration.

5)☐ Claim(s) ____ is/are allowed.

6)☐ Claim(s) ____ is/are rejected.

7)☐ Claim(s) ____ is/are objected to.

8)☒ Claim(s) *1-147* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on ____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on ____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. ____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-14, drawn to a method of treating gastritis and peptic ulcer diseases comprising administration of an oral liquid dosage form containing bile acid, starch or non-starch polysaccharide and water

II. Claims 15- 22, drawn to a method for treating a liver diseases comprising administration of an oral liquid dosage form containing bile acid, starch or non-starch polysaccharide and water .

III. Claims 23-27, drawn to a method for treating gall stones comprising administration of an oral liquid dosage form containing bile acid, starch or non-starch polysaccharide and water

IV. Claims 28-36, drawn to a method for treating or preventing colorectal adenoma comprising administration of an oral liquid dosage form containing bile acid, starch or non-starch polysaccharide and water

V. Claims 37-47 , drawn to a method for treating hyperlipidemia comprising administration of an oral liquid dosage form containing bile acid, starch or non-starch polysaccharide and water.

VI. Claims 48-77, 81 and 138-147, drawn to a clear aqueous composition comprising a bile acid or its analogs, an aqueous soluble non-starch polysaccharide and water.

VII. Claims 78-80, drawn to a method of preparing an aqueous solution of group VI.

VIII. Claims 82-87, drawn to a clear aqueous solution comprising a bile acid containing first material, a second material containing an aqueous soluble starch or non-starch polysaccharide, a third material comprising an aqueous soluble bismuth compound and water.

VIIII. Claims 97-128, drawn to a method of increasing or decreasing the enterohepatic bile acid ; increasing the blood concentration of intact bile acid ; or increasing or decreasing absorption and elimination of intact bile acid comprising administration of an oral liquid dosage form containing bile acid, starch or non-starch polysaccharide and water.

2. Inventions (VI or VIII) and (I-V, VIIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

3. Inventions (VI or VIII) and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)).

4. Inventions I, II, II, IV, V and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

5. Inventions V and VIII are independent and distinct, each from the other, as they have acquired a separate status in the art and/or require independent searches. It is noted that a reference to one combination of drugs would not be a reference to another combination of drugs under U.S. C. 103. Further, the claims read on a multitue of combinations of drugs which would require many field of searches that would be an undue burden on the examiner. Therefore, restriction for examination purposes is proper.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the search required for each group is not same, wherein a reference which anticipates the invention of Group I would not render the invention of Group II or III obvious, absent ancillary art, restriction for examination purposes as indicated is proper. Even if there were unity of classification, the search of entire groups and/or genus in the non-patent literature(especially, non-patent literature) and database search (a significant part of a thorough examination) would be burdensome, it is undue burden for examiner for the accurate and proper examination, restriction for examination purposes as indicated is proper.

Election of speice

7. Upon the election of the group that contains patentably distinct invention, applicant is further required to elect the speicies of the each component. This application contains claims directed to the following patentably distinct species of the claimed invention: Firstly, the claims include various bile acid analogs including bile acid, its salts , its derivatives and a bile acid conjugated with an amine. For instance, Claim 61 is listing various patentably distinct species of bile acid. Secondly the claims include patentably distinct species found in second material(e.g. starch conversion product or non-starch polysaccharide). In the case of that group VIIII is elected, applicant is required to elect the species mentioned immediately above(i.e. first and second material) and found in specific utility(i.e claim 97, 104, 111, 120 or 129).

The various sets of combinations comprising different first material and second material are independent and distinct, each from the other, as they have acquired a separate status in the art and/or require independent searches.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

All the pending claims are subject to restriction/election requirement.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is (703) 305-1675 (Tuesday-Friday: 8AM-6:30PM).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Vickie Kim,
Patent examiner
May 29, 2002
Art unit 1614